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EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,567	RUCHALA ET AL.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/28/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Regarding claim 23, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 8-9, 15, 19-20, 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosman (US Pat: 6,405,072).

Regarding claims 1, 3 and 25, Cosman teaches that anticipates the claimed invention. Cosman teaches a system for positioning and repositioning of a portion of a patient's body with respect to a treatment or imaging machine includes multiple cameras to view the body and the machine. Index markers, either light-emitting, passive, geometric shapes, or natural landmarks, are identified and located by the cameras in 3D space. In one embodiment, such reference or index markers are in a determinable

relationship to analogous markers used during previous image scanning of the patient. Anatomical targets determined from image scanning can be located relative to reference positions associated with the treatment or diagnostic machine. Several forms of camera, index markers, methods and systems accommodate different clinical uses. X-ray imaging of the patient further refines anatomical target positioning relative to the treatment or diagnostic imaging reference point [see abstract].

Cosman teaches a set of markers (20, 21, 23 and 24) can be "seen" by the cameras to track marker positions relative to the isocenter point and the beam [see column 4 lines 63-67]. Another set of markers (30, 31 and 32) are attached to the couch F, shown variously disposed on the couch top 11 [see fig 1, 3A and 3B, 5, 11). The markers also are detected by the camera system C to determine the orientation of the couch F relative to the camera system C. Thus, by using outputs from the camera system C, the processor also provides data indicating the position of the couch F in camera space. Utilizing such data, the processor functions with other components of the treatment processing system T to coordinate data and accomplish the functions as described above. Other components of the treatment processing system T include an imager, a treatment and planning system, a comparator/computer, a controller coupled to a manual input and an interface display unit. The detailed operation of the treatment processing system T is treated below [see column 5 lines 20-33].

Cosman teaches another set of index markers (40A, 40B and 42C, see fig 11) is fixed on the gantry, also to indicate positions in camera space. Furthermore, markers are fixed on the collimator (end of the gantry) specifically to enable three-dimensional

tracking of the gantry and the beam B relative to the patient P and the couch F. Thus, the camera system C provides data to coordinate the treatment machine L, the beam B relative to the patient P, aligning an anatomical target with the beam B at the isocenter point, or other focus of radiation [see column 5 lines 36-43].

Cosman teaches many variations of the camera form, numbers, positioning, and relative calibration are possible. Various types of treatment machines such as LINACs, proton accelerators, ultrasonic machines, interventive radiofrequency devices, interventive stereostactic apparatus of all types, as well as diagnostic machines such as CT, MR, PET, ultrasound, MEG scanners can substitute as the apparatus in the above embodiments. A variety of index markers, either surface mounted, implanted, of geometric area type, skin bands, linear and geometric structures taped to the skin, and so on can be used as referencing during historic imaging and treatment or diagnostic positioning. Various process steps can be used to implement the patient target positioning and movement of the patient to bring an anatomical region into desired relationship or relative to a predetermined position or volume within the treatment or diagnostic machine [see column 21 lines 45-62].

Regarding claim 26, all other limitations are taught as set forth by the above teaching.

Cosman teaches patient is placed on a LINAC treatment table [see fig 11] with a calibrated camera set and with appropriate registration or index markers on the patient and the LINAC apparatus, then all of the physical objects such as the patient's body,

the treatment couch, and the LINAC collimator can be detected and can be mapped into the coordinate system defined by the isocenter and the laser axes. The use of orthogonal lasers to define isocenter is commonly used in modern day LINAC treatment setups [see column 20 lines 1-14]. As taught by Cosman in fig 11, the couch which includes a plurality of index markers is flat. A variety of index markers, either surface mounted implanted, of geometric area type [see column 21 lines 45-62].

Regarding claims 8-9, and 12, all other limitations are taught as et forth by the teaching of Cosman above.

Cosman further teaches a variety of index markers, either surface mounted, implanted, of geometric area type, skin bands, linear and geometric structures taped to the skin, and so on can be used as referencing during historic imaging and treatment or diagnostic positioning. Various process steps can be used to implement the patient target positioning and movement of the patient to bring an anatomical region into desired relationship or relative to a predetermined position or volume within the treatment or diagnostic machine [see column 21 lines 45-62]. Taping markers to the skin as taught above, meaning that the markers are in fact removable, because taping the index marker to one location of the skin and one can untape or remove the index marker and tape it on a different location (emphasis added). As taught by Cosman, the above teaching of disclosure is used to calibrate and position a radiation treatment couch (table as called by Applicant), the gantry, the patient etc... Cosman teaches index markers that located to the sides of the treatment couch and table [see fig 11].

Regarding claim 15, all other limitations are taught as set forth by the above teaching of Cosman.

Cosman also teaches Index markers (20, 21, 23 and 24) are fixed on the patient as previously described with reference to FIG. 1. Recall that these markers identify locations marked by radiopaque or MR (magnetic resonance) detectable index markers fixed on the patient P at the time of the CT or MRI scanning. The arrangement in FIG. 2 could be applied on the simulator couch top 11 (meaning fix the MR markers to the couch) to simulate a preplan of the treatment setup or could be applied on the couch for radiotherapy as for example a LINAC couch. The radiopaque or MR detectable index markers used during the CT or MR scanner phase can be replaced in the arrangement of FIG. 2 by camera detectable index markers placed at the same locations on the patient [see column 8 lines 5-20].

Regarding claims 19-20, and 22-24, all other limitations are taught as set forth by the above teaching of Cosman. Fig 11 shows the markers are disjoint and solid.

Cosman further teaches at least three different set of markers for different objectives. Cosman teaches another set of index markers (40A, 40B and 42C, see fig 11) is fixed on the gantry, also to indicate positions in camera space. Cosman teaches a set of markers (20, 21, 23 and 24) can be "seen" by the cameras to track marker positions relative to the isocenter point and the beam [see column 4 lines 63-67]. Another set of markers (30, 31 and 32) are attached to the couch F, shown variously

disposed on the couch top 11 [see fig 1, 3A and 3B, 5, 11). The markers also are detected by the camera system C to determine the orientation of the couch F relative to the camera system [see column 5 lines 20-33].

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 4-7, 10-11, 13-14, 17-18, 27-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman (US Pat: 6,405,072) in view of Seeley et al (US Pat: 6,484,049).

Regarding claims 2, 4-7, 10-11, 27-30, all other limitations are taught as set forth by the above teaching. Applicant describes high and low density material in the form of solids as (wire, pellets, ball, and paste) and liquids (column of water, bubble level) [see 0010, see Application specification]. Applicant also teaches marker material could be tungsten wire [see 0029, see Application specification], high density (wire inlay), contrast inserts or resolution inserts could be embedded or molded into the table [see 0039, Application specification].

Cosman doesn't disclose of what materials the index markers and the table are made of; and embedding index markers into treatment table.

However, Cosman teaches the index markers are implantable and are surface mounted meaning they can be embedded into a surface as taught above. Cosman teaches index markers that are surface mounted and can be implanted to surface [see column 21 lines 45-62]. Cosman also teaches index markers that fixed or mounted to a radiation couch or table [see fig 11].

Seeley et al teach a suitable marker array calibration fixture or standard ST and may include several sheets of radiolucent material each holding an array of radiopaque point-like markers, such as stainless steel balls (Hereafter simply referred to as BBs). The BBs may be of different sizes in the different planes, or may be of the same size. Seeley et al also teach marker plates may each be manufactured by NC drilling of an array of holes in an acrylic, e.g., Lexan, and/or other polymer plate, with the BBs pressed into the holes, so that all marker coordinates are exactly known. Alternatively, marker plates may be manufactured by circuit board microlithography techniques, to provide desired patterns of radiopaque markers, for example as metallization patterns, on one or more thin radiolucent films or sheets. Applicants also contemplate that the calibration assembly, rather than employing separate sheets bearing the markers, may be fabricated as a single block 50 of a suitable radiolucent material such as a structural foam polymer having a low density and high stiffness and strength [see column 11 lines 22-33].

In FIG. 3A, holes may be drilled to different depths and BB markers may be pressed in to defined depths Z.sub.1, Z.sub.2 . . . At specific locations to create the desired space array of markers in a solid foam calibration block. One suitable material

of this type is a structural foam of the type used in aircraft wings for lightweight structural rigidity. This material may also be employed in separate thin marker-holding sheets. In any case the selected polymer or foam, and the number and size of the markers, are configured to remain directly in the imaging beam of the fluoroscope device and be imaged in each shot, while the position of the fixture is tracked [see column 11 lines 45-53]. The fixture materials are selected to avoid introducing any significant level of x-ray absorption or x-ray scattering by the plates, sheets or block [see column 11 lines 35-60].

Seeley et al teach all or a portion of the marker array assembly implemented with markers located on or in a radiographic support table (75, FIG. 6) or other structure on which the patient or the imaged tissue portion is supported. In this case, the table or support itself, which is radiolucent, may have a thickness and structure that permits markers to be embedded at different depths. For example, it may be formed of a structural foam material as described above in regard to the marker fixture of FIG. 3A. Alternatively, the markers may be included in one or more sheets that fit within the x-ray sheet film tray of a conventional radiography table or such marker sheets may be laminated to the bottom and/or top surfaces of the table [see column 18 lines 50-63].

Seeley et al teach fluoro-CT images thus constructed may be directly registered to preoperative MRI, CT or PET 3D image data, or may obviate the need for such preoperative imaging. Preferably, the tracker employs electromagnetic tracking elements, to generate and/or detect electromagnetic field components unobstructed by the patient and intervening structures, and to determine coordinates directly referenced

to the patient, the tool or the camera. The calibration fixture may be implemented with BBs in a radiolucent block of structural foam, and/or may be implemented by microlithographic techniques, in which case magnetic tracking elements may be simultaneously formed in registry with the markers on a sheet that mounts to the camera, is incorporated in a radiographic support table or otherwise positioned to be imaged in each shot [see abstract and see fig 6].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by using a marker made of polymer material which has a low density as taught by Seeley et al and the treatment table made of stainless steel or magnetic as taught above by Seeley et al; in order to

One with ordinary skill in the art at the time the invention was made would have been motivated to modify the Cosman reference by embedding index markers into treatment table; for the purpose of fixing the markers to the treatment table for stability so they can move as a unit.

Regarding claims 13-14, all other limitations are taught as set forth by the above combination. Cosman teaches a desired placement position for a radiopaque apertured disk or marker detectable during the scanning; a retro reflective apertured disk; an aperture or hole is defined in the center of the disk [see fig 2].

Cosman doesn't teach index markers are a protrusion, indentation or groove.

However, Seeley et al teach affixed to the table or inserted in a registered or fixed fashion, the tracking element may then be attached anywhere on the rigid

structure of the table itself, with suitable offsets stored in a fixed memory element of the system [see column 18 lines 64-67].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by indent the markers into the table and on a protrusion; for the purpose of securely attach index markers to the table and push in or cave in the markers so that they don't bump the patient while laying on the table or couch.

Regarding claims 17-18, all other limitations are taught as set forth by the above combination.

Cosman doesn't teach index markers are RF emitters or detectors.

However, Cosman teaches the markers may take a variety of forms, for example, LED emitters, reflectors of light, reflecting spheres, reflecting dots or various other devices that can be tracked by the camera system in three-dimensional space [see column 4 lines 38-44].

However, Seeley et al teach markers could be emitters [see above].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references by using RF emitters or receivers; for efficiency and reliability.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman (US Pat: 6,405,072) in view of Kalend et al (US Pat: 5,823,192).

Regarding claim 16, all other limitations are taught as set forth by the above teaching. Cosman teaches recognizing that various forms of markers can be used, if the index markers are of the reflecting type, a light source (infrared) may be used to produce reflected.

Cosman is silent to index marker is a laser.

However, Kalend et al teach in fig 2 and column 4 lines 42-50] laser markers or cross are used to accurately position a patient and treatment diagnostic device.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Cosman and Kalend et al references by using laser marker; because it can enhance the signal-to-noise ratio of the reflected light from the index markers as related to background.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman (US Pat: 6,405,072) in view of Orser (US Pat: 2,506,887).

Regarding claim 21, all other limitations are taught as set forth by the above teaching.

Cosman is silent to a liquid marker.

However, Orser teaches liquid marker that can be applied to surfaces [see column 5 lines 28-34].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Cosman and Orser references by using liquid marker; in order to be placed on the table easily.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768